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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/379,308	08/23/99	DIAZ	P 016800-318

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EXAMINER	
LUKTON, D	
ART UNIT	**PAPER NUMBER**
1653	9

DATE MAILED: 08/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.	Applicant(s)
09/379,308	Diaz
Examiner	**Group Art Unit**
David Lukton	1653

THE PERIOD FOR RESPONSE: [check only a) or b)]

a) ☐ expires _____ months from the mailing date of the final rejection.

b) ☒ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on _____ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on *Jul 18, 2000* **has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:**

☒ The proposed amendment(s):

- ☒ will be entered upon filing of a Notice of Appeal and an Appeal Brief.
- ☐ will not be entered because:
  - ☐ they raise new issues that would require further consideration and/or search. (See note below).
  - ☐ they raise the issue of new matter. (See note below).
  - ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
  - ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

☐ Applicant's response has overcome the following rejection(s):

_____

☐ Newly proposed or amended claims _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attached sheets.

☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: *none*

Claims objected to: _____

Claims rejected: *28-30, 34-36, and 38-41*

☐ The proposed drawing correction filed on _____ ☐ has ☐ has not been approved by the Examiner.

☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ .

☐ Other

Advisory Action

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-30, 34-36, 38-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have submitted a declaration asserting that (a) a few of the disclosed compounds have exhibited activity in an *in vitro* assay, (b) the results of this assay suggest that the disclosed compounds are retinoids, (c) retinoids, as a general proposition, are effective to treat cancer, and (d) the "retinoic acitivity" of one of the disclosed compounds was demonstrated in an assay:

> "which measures the effect of compounds according to the invention on ear oedema induced by topical administration of a compound according to the invention".

No copy of any of the publications describing the nature of the assay has been provided. Assays vary considerably with respect to their specificity and reliability. For example, a simple assay for competitive binding to a receptor is of little predictive value, and subject to artifact. But even if it is true that some of the disclosed compounds will exhibit one

or two activities in common with certain retinoinds, it does not follow therefrom that the disclosed compounds will share all properties with retinoids. Moreover, it is not the case that all "retinoids" are effective to treat any one form of cancer. Perhaps there are certain receptors to which both retinoids and the disclosed compounds will bind to. But the receptors which are most critical to the development of a given form of cancer might not recognize any of the disclosed compounds at all.

With respect to assertion (d) above, it appears from applicants statement that the compound in question was used first to induce the ear oedema, and subsequently to treat it. The methodology is not clear; nor have any experimental details been provided. But more importantly, no relationship between ear oedema (on the one hand) and cancer (on the other hand) has been established.

Moreover, even if it were true that all of the disclosed compounds can eradicate all forms of cancer, the claims would still be far from being enabled. Claim 28 is drawn to a method for treating "a dermatological condition". How is acne, for example, related to cancer? Are antineoplastic compounds generally effective in the treatment of e.g., psoriasis or eczema? In addition to the foregoing, applicants have made no attempt to defend their assertion that the compounds can be used to treat diabetes. Claim 40 remains rejected without further argument.

In sum, applicants data falls far short of what would be needed to support even one of the numerous disorders encompassed by the claims. Applicants have failed to establish that

one can extrapolate from the limited *in vitro* data provided to a general therapy for dermatological disorders, cancer, or diabetes. The rejection is maintained.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Christopher S. F. Low

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